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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,997	12/15/2000	James G. Keck	24743-2307US	5984
20985 7	590 05/22/2006		EXAM	INER
FISH & RICHARDSON, PC			EPPS FORD, JANET L	
P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
	,		1633	
			DATE MAILED: 05/22/2006	6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
09/601,997	KECK, JAMES G.	
Examiner	Art Unit	
Janet L. Epps-Ford	1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 20 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires \_\_\_\_\_months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action, or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** 2. The Notice of Appeal was filed on 20 April 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). AMENDMENTS 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. For purposes of appeal, the proposed amendment(s): a) uill not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 8-14 and 58-73 would remain rejected for the reasons of record. Claim(s) withdrawn from consideration: . . AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. 

The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached communication. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_ 13. Other: \_\_\_\_. Janet L. Epps-Ford Primary Examiner Art Unit 1633

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#### **DETAILED ACTION**

#### Response to Arguments

#### Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 8-14, and 58-74 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rejected was necessitated by Applicant's amendment to the claims filed 8-03-05.
- 3. Applicant's arguments filed 4-20-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the claims as amended should place the case in condition for allowance, since the claims as amended clarifies that the transcription product is antisense to the target mRNA, *i.e.*, no additional antisense molecule other than the transcription product is recited in the claims. Contrary to Applicant's assertion, Applicant's amendment does not place the case in condition for allowance since the nature of the claimed invention remains vague and indefinite.

Claim 8, and 58 as amended recites the following: "the coding *sequences* for each individual **transcription products** encodes an antisense nucleic that, **when expressed as RNA**, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence..."

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The metes and bounds of the above phrase remain vague and indefinite. It is the examiner's understanding that the process of transcription produces an RNA molecule, therefore a "transcription product" would necessarily comprise RNA. Therefore the phrase, "when expressed as RNA," is vague and indefinite since it is the examiner's understanding that the antisense nucleic acid is in the form of RNA.

### Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 8-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent No. 6,355,415 B1) in view of Gudkov et al. (US Patent No. 5,753,432), for the reasons of record.
- 6. Applicant's arguments filed 4-20-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the invention of Wagner et al. is limited to the use of computer-based conformational modeling for the identification of accessible cleavage sites. Contrary to Applicant's assertions, the invention of Wagner et al. is not so limited, Wagner et al. expressly states:

"[T]he invention is not limited to substrate cleavage sequences located in unpaired regions or loop structure, or to the number of ribonucleotide in these regions and structures. Cleavage sequences of any length may be located anywhere in a substrate RNA so long as a ribozyme is capable of cleaving at or near the substrate cleavage site. (see col. 19, lines 15-20)

Moreover, Gudkov et al. as stated in the prior Office Action, Gudkov et al. reference is relied upon since it provides specific guidance for amplifying and expressing the oligonucleotide constructs of the instant invention in cells without the use of bacterial cloning steps. Gudkov et al. provide methods for designing a retroviral library of nucleic acid fragments to be delivered to eukaryotic cells to test or determine the ability of these nucleic acid fragments to function as genetic suppressor elements (GSE) (see col. 10-12). The methods of Gudkov et al. essentially comprise methods for identifying gene function since the ability of the putative nucleic acid molecules to function, as a GSE is unknown prior to testing.

Absent evidence to the contrary, As stated in the prior Office Action, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the teachings of Wagner et al. with the teachings of Gudkov et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to make this modification since Wagner et al. expressly states that their disclosed methods for determining gene function may encompass wherein the transfection method comprises the use of retroviral vectors, and the teachings of Gudkov et al. are specifically designed to deliver nucleic acid to cells using retroviral vectors with the express purpose of determining their ability to alter a phenotype of the transfected cells.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JLE

PRIMARY EXAMINER